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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,845	10/15/2003	Michael T. Lotze	UPT-004	9535

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EXAMINER

LIETO, LOUIS D

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/688,845

**Applicant(s)**

LOTZE ET AL.

**Examiner**

Louis D. Lieto

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27, drawn to a method of inhibiting or treating a tumor in a subject, with an effective amount of an APC and an immunostimulatory cytokine, classified in class 424, subclass 93.1.
- II. Claims 1-12 and 27, drawn to a method of inhibiting or treating an infectious lesion in a subject, with an effective amount of an APC and an immunostimulatory cytokine, classified in class 424, subclass 93.1.
- III. Claims 1-27, drawn to a method of inhibiting or treating a tumor in a subject, with an effective amount of an APC and a nucleic acid encoding an immunostimulatory cytokine, classified in class 514, subclass 44.
- IV. Claims 1-12, and 27 drawn to a method of inhibiting or treating an infectious lesion in a subject, with an effective amount of an APC and a nucleic acid encoding an immunostimulatory cytokine, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are patentably distinct inventions for the following reasons. In the instant case the different invention of group I is drawn to a method of inhibiting or treating a tumor in a subject, with an effective amount of an APC and an immunostimulatory cytokine, while the invention of group II is drawn to a method of inhibiting or treating an infectious lesion in a

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subject, with an effective amount of an APC and an immunostimulatory cytokine, invention of group III is drawn to a method of inhibiting or treating a tumor in a subject, with an effective amount of an APC and a nucleic acid encoding an immunostimulatory cytokine, while the invention of group IV is drawn to a method of inhibiting or treating an infectious lesion in a subject, with an effective amount of an APC and a nucleic acid encoding an immunostimulatory cytokine. The inventions of groups I and II are materially different from the inventions of groups III and IV, because the first set requires the use of a cytokine to practice the invention, while the invention of the second set requires the use of a nucleic acid encoding a cytokine in order to practice the invention. Further, the methods of groups II and IV are different from the methods of groups I, and III. An infectious lesion comprises the additional presence of an infectious agent, which is materially different in both pathology and prognosis from a tumor.

Furthermore, searching the inventions of groups I-IV together would impose a serious search burden. In the instant case, the search of a method of treating tumors, infectious lesion, metastasis, a cytokine and nucleic acid encoding a cytokine and a therapeutic composition are not co-extensive. As such, it would be burdensome to search the inventions of groups I-IV together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

1. This application contains claims directed to the following patentably distinct species of the claimed invention: The inventions of groups I -III list the following patentably distinct species of antigen presenting cells:

- a. a CD34+ derived dendritic cell
- b. a bone marrow derived dendritic cell
- c. a monocyte-derived dendritic cell,
- d. a splenocyte derived dendritic cell,
- e. a skin-derived dendritic cell
- f. a follicular dendritic cell
- g. a germinal center dendritic cell
- h. a Langerhan's cell
- i. an interdigitating cell
- j. a B Cell
- k. a macrophage

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26 are generic.

2. This application contains claims directed to the following patentably distinct species of the claimed invention: The inventions of groups I-IV list the following patentably distinct species of immunostimulatory cytokines or nucleic acid encoded cytokines:

Applicant is required to elect one of the cytokines or nucleic acid encoded cytokines listed in claim 6 or 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-27 are generic.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: The inventions of groups I, III list the following patentably distinct species of tumors:

Applicant is required to elect one of the tumors listed in claim 9 or 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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